RESULTS OF INVESTIGATION: The 14-vial lot was the "*Laetrile*" product which had been relabeled by the dealer as "*Formula L.*"

LIBELED: 12–28–60, N. Dist. Tex.

CHARGE: 505(a)—the article was a new drug which may not be introduced into or delivered for introduction into interstate commerce since it was sold for investigational purposes and was not being so used, and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 2–7–61. Default—delivered to the Food and Drug Administration.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

6544. Penicillin G tablets. (F.D.C. No. 45448. S. No. 26–857 R.)

QUANTITY: 43 100-tablet btls. at Los Angeles, Calif.

SHIPPED: 8–16–60, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LIBELED: 3–8–61, S. Dist. Calif.

CHARGE: 502(l)—when shipped, the article was composed in whole or in part of penicillin and was from a batch with respect to which a certificate or release had not been issued pursuant to 507 in that effective exemption or supplemental certification of the batch had not been obtained.

DISPOSITION: 3–30–61. Default—destruction.

DRUG FOR VETERINARY USE

6545. Dihydrostreptomycin tablets. (F.D.C. No. 45511. S. No. 61–028 R.)

QUANTITY: 3 drums, each containing 11,500 tablets, 1 drum containing 600 tablets, and 125 100-tablet btls., at St. Joseph, Mo., in possession of United Pharmacal Co., Inc.

SHIPPED: 7–30–58, from Buffalo, N.Y.

LABEL IN PART: (Drum) "Special Formula S/F Tablets—Uncoated Expiration Date July 1960 7–30–58 Manufactured for United Pharmacal Co. * * * St. Joseph, Missouri * * * Formula No. 159,700 Lot 1 UPC–1 * * * Each tablet contains: Dihydrostreptomycin Base (as Sulfate) 50 mg. Pectin 37 mg. Kaolin 417 mg. Hydrated Alumina Powder 126 mg. For treatment of gastroenteritis, enteritis and diarrhea (due to dihydrostreptomycin sensitive organisms) in cats and dogs" and (btl.) "UPCO * * * 'K.P.S.–630' Dihydrostreptomycin Sulfate with Kaolin, Alumina, and Pectin. Each tablet contains * * * Distributed by United Pharmacal Company, St. Joseph, Mo."

RESULTS OF INVESTIGATION: The article in the bottles was repacked and labeled by the dealer after shipment as described above.

LIBELED: On or about 3–16–61, W. Dist. Mo.

CHARGE: 502(l)—while held for sale, the article purported to be and was represented as a drug composed in part of dihydrostreptomycin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 5–5–61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6546. Various drugs. (Inj. No. 335.)

COMPLAINT FOR INJUNCTION FILED: 6–24–58, N. Dist. N.Y., against Delmar Pharmacal Corp., Rensselaer, N.Y.

NATURE OF BUSINESS: The defendant was engaged in manufacturing, preparing, packing, selling, and distributing directly in interstate commerce, and delivering to the Rand Pharmaceutical Co., Inc., and Previcol, Inc., Rensselaer, N.Y., for sale and distribution in interstate commerce, various articles of drug.

CHARGE: The complaint alleged that the defendant was introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, various articles of drug which were adulterated and misbranded in the following respects:

(a) A number of articles of drug were adulterated within the meaning of 501(b), in that said articles purported to be drugs, the names of which were recognized in an official compendium, the U.S. Pharmacopoeia, and their strength differed from the standards set forth in such compendium;

(b) A number of articles of drug were adulterated within the meaning of 501(c), in that they were not subject to the provisions of 501(b) and their strength differed from, and their quality fell below, that which they purported and were represented to possess;

(c) A number of articles of drug were misbranded within the meaning of 502(a), because of false and misleading statements in the labeling of said articles with respect to the nature and quantity of the ingredients;

(d) A number of articles of drug were misbranded within the meaning of 502(d), in that they were drugs for use by man and they contained a quantity of narcotic or hypnotic substance, or a chemical derivative of such substance, which derivative had been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming, and their labels failed to bear the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming";

(e) A number of articles of drug were misbranded within the meaning of 502(e)(2), in that they were drugs not designated solely by a name recognized in an official compendium and they were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient;

(f) A number of articles of drug were misbranded within the meaning of 502(f)(1), because their labeling failed to bear adequate directions for use in that the recommended or usual dose was omitted; and

(g) A number of articles of drug were misbranded within the meaning of 503(b)(4), in that they were drugs within the meaning of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The complaint alleged further that the adulterated and misbranded condition of said articles of drug resulted from deficiencies in the ingredients of said articles, or the presence in said articles of drug of ingredients in amounts in excess of those declared on the labels, which were due to inadequate manufacturing facilities, lack of identification control, lack of adequate analysis and formulas, or lack of other precautions essential to the compounding of potent

drugs, for example, the *digitalis tablets* contained 74.7 percent of the declared amount of digitalis; the *digitoxin tablets 0.1 mg.* contained 82.9 percent of the declared amount of digitoxin; the *Diphylets tablets, TDC*, contained 90.5 percent of the declared amount of dextro-amphetamine sulfate, were shipped in bulk without the statement "Caution: Federal law prohibits dispensing without prescription" on the label and the label further failed to list the ingredients contained in said article of drug; the labels of the *Reducing tablets—green* and *Reducing tablets—pink* failed to contain the statements "Caution: Federal law prohibits dispensing without prescription," and "Warning—May be habit forming," and the recommended or usual dosage; the *#0 Pink Reducing capsules* were 15.7 percent deficient in dextro-amphetamine sulfate, the two lots of *Del-Bardex #1 Timed Disintegration capsules* were from 23.3 percent to 29 percent deficient in dextro-amphetamine sulfate and were from 20.9 percent to 36 percent deficient in amobarbital; the *Del-Bardex #2 Timed Disintegration capsules* released 80 percent of the active ingredients therein within 2 hours rather than the period of 6–10 hours alleged on the label; the *Special Formula tablets, Cocoa Brown*, were 30 percent deficient in desoxyephedrine hydrochloride; the bulk shipment of *Span RD capsules #1* failed to bear a label containing the statements "Caution: Federal law prohibits dispensing without prescription" and "Warning—May be habit forming" and the recommended or usual dosage; the *Del-O-Bex 30 Timed Disintegration capsules* were 10.4 percent deficient in dextro-amphetamine sulfate and 8.8 percent deficient in phenobarbital; the *Del-O-Bex 15 TDC capsules* were 15 percent deficient in dextro-amphetamine sulfate; the statement, to wit, "Warning—May be habit forming" on the label of the *pentobarbital sodium capsules 1½ gr.* was not in juxtaposition with the name of the drug contained therein; the bulk shipment of *Del Caps 10 mg. TDC capsules* was labeled as containing both 10 mg. and 15 mg. capsules and the major portion of the drug within said capsules was released very rapidly rather than over a 6–10 hour period as alleged on the label; of the six lots of *Del Caps 15 TDC capsules*, four released from 80–94 percent of the dextro-amphetamine sulfate within 2 hours rather than over a period of 6–10 hours as alleged on the label, one lot was 23 percent deficient in dextro-amphetamine sulfate, one lot, a bulk shipment of said drug, failed to bear a label with the statement "Caution: Federal law prohibits dispensing without prescription" and the recommended or usual dosage, and one lot bore a statement on the label, to wit "Each capsule is equivalent to one tablet of 5 mg. Dextro-Amphetamine Sulfate taken two times a day" whereas each capsule contained 15 mg. dextro-amphetamine sulfate and released 10 mg. of the 15 mg. contained therein within two hours; the *Amphetidisin—10 TDC capsules* released 88 percent of the dextro-amphetamine sulfate contained therein within 2 hours rather than over a period of 6–10 hours as alleged on the label; the *Trim-All Caps TDC capsules* were from 23–29 percent deficient in phenylpropanolamine hydrochloride, from 36–38 percent deficient in ascorbic acid and released 90 percent of the active ingredients within two hours; the *dextro-amphetamine sulfate tablets, 5 mg.* contained 25 percent excess dextro-amphetamine sulfate; the *dextro-amphetamine sulfate tablets, 10 mg.* contained 113 percent of the declared amount of dextro-amphetamine sulfate, failed to bear the statements on the label "Caution: Federal law prohibits dispensing without prescription," and failed to state the recommended or usual dosage; the bulk shipment of *Special Formula capsules* failed to bear a label containing the statements "Caution: Federal law prohibits dispensing without prescription," "Warning—May be habit forming" after

the barbiturate declaration, and the recommended or usual dosage; and the *Del Hist 75 mg. capsules* were 11.1 percent deficient in pyrilamine maleate.

The complaint alleged further that the defendant was well aware that its activities were violative of the Act. Thirteen inspections were made of the defendant's plant at Rensselaer, N.Y., by inspectors of the Food and Drug Administration between 10–4–54 and 12–20–57, at which inspections the defendant was informed of certain inadequacies in its control system for the manufacture of articles of drug, namely, the failure to assay raw materials used, failure to retain reserve samples, failure to clearly identify containers, re-use of bulk containers with old labeling, the lack of an adequate checking system to insure that the proper amounts of various chemicals were used in the batches being processed, and the practice of making very few assays of the finished articles. The defendant was warned of the inadequacies encountered. The defendant had been warned further by eleven seizures of articles of drug which were adulterated and misbranded; by hearings pursuant to 305 of the Act; and by a criminal prosecution against the defendant and its former general manager for violation of the Act, which action was terminated upon a plea of guilty by the defendant and its former general manager, resulting in a fine of $750 against the defendant corporation.

DISPOSITION: On 7–22–58, a consent decree of permanent injunction was filed. The consent decree enjoined the defendant from directly or indirectly introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any article of drug that was adulterated or misbranded under the Act unless and until:

(a) Sufficient qualified and experienced personnel, including supervisory personnel, is employed in the plant to properly operate it.

(b) A properly qualified pharmaceutical chemist is employed to make sufficient analyses of each batch of finished drug to insure that it conforms to the labeling under which it is to be shipped and to the requirements of the National Formulary or U.S. Pharmacopeia or other standard which may be applicable. Lacking this, a representative sample of each finished batch of drugs is submitted to a reliable established outside laboratory for examination prior to shipment.

(c) A system of properly identifying and storing raw materials as they are received at the plant.

(d) Batches of drugs in preparation are not manipulated in an improper manner resulting in unwarranted shortages or overages in the final yield.

(e) Sampling of finished tablets and all other finished products is done in a representative manner to insure the taking of a representative, adequate sample.

(f) Capsules are assayed in finished form rather than in earlier stages of manufacture.

(g) The practice of shipping finished batches of drugs prior to analysis or without analysis is discontinued.

(h) The distribution of new drugs without effective new drug applications is discontinued.

(i) At least one qualified person in the plant has sufficient information concerning the new drug shipped from this plant to eliminate confusions and violations.

(j) Adequate samples of incoming raw materials are taken and appropriate analysis of these samples made.

(k) Preparation of manufacturing records and forms is done with such clarity, care and completeness as to eliminate mistakes and confusion.

(l) Operations involving the weighing out of raw materials and the preparation of formulae and application of labeling are checked by another qualified party in addition to the employee originally performing such duties.

(m) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion, and the possibility of mistakes.

(n) A representative of the U.S. Food and Drug Administration inspects the plant and determines that an adequate control system has been installed embodying all of the herein listed safeguards considered necessary to good pharmaceutical manufacturing practice.

6547. Menestrex capsules. (F.D.C. No. 43564. S. No. 56–778 P.)

QUANTITY: 660 12-capsule btls. and 108 25-capsule btls. at Atlanta, Ga.

SHIPPED: 6–8–59 and 7–13–59, from Nashville, Tenn., by Rex Laboratory.

LABEL IN PART: "Menestrex * * * Contains: Potassium Permanganate Quinine Sulphate."

LIBELED: 9–25–59, N. Dist. Ga.; amended libel filed 2–2–61.

CHARGE: 502(a)—when shipped, the bottle label bore false and misleading representations that the article was an adequate and effective treatment for easing distress in scanty or functionally difficult menstruation; 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use and the article was not exempt from that requirement; 503(b)(4)—while held for sale, the article was subject to 503(b)(1)(B) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Rex Laboratory, claimant, filed an answer denying that the article was misbranded as alleged and moved for a transfer of the case to another district. On 12–16–59, the court issued the following order:

HOOPER, *District Judge:* "Claimant has moved to transfer the trial of this action to 'a proper district of reasonable proximity to his principal place of business,' his business being located in Nashville, Tennessee, in the Middle District of Tennessee.

"He suggests removal to the Winchester Division of the Eastern District of Tennessee.

"His motion is based upon provisions of *21 U.S.C.A. § 334(a)*, which makes it mandatory upon the Court in a case of this nature to transfer the case, but there is an exception made in cases 'when such misbranding has been the basis of a prior judgment in favor of the United States in a . . . libel for condemnation proceedings under this chapter.'

"The Government resists the removal upon the sole ground that allegedly there have been 'prior judgments in this district condemning the exact same product.' Attached to the Government response are copies of three libels filed in this district concerning the same shipper and the same product and in two of the libels there is involved the same alleged misbranding, to-wit, that the libels 'are false and misleading since the article is not effective' in the treatment of the ailments involved.

"However, one of these libels was filed October 20, 1948, and it does not appear whether a judgment was taken or whether the proceeding was even opposed. The other libel was filed October 28, 1948, nothing appearing but copy of the libel petition.